



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

December 9, 1982

OFFICE OF
THE ADMINISTRATOR

Mrs. Anne M. Gorsuch
Administrator
U.S. Environmental Protection Agency
Washington, D.C. 20460

Dear Mrs. Gorsuch:

During the past year the Science Advisory Board's Environmental Health Committee has spent essentially all of its time reviewing a series of health assessment documents. As you are aware, these are multi-purpose documents that are intended to support the Agency's regulatory actions under several statutes.

During the course of the review of these assessment documents the Agency staff and the committee members have identified short-comings in the supporting data bases that impact on our confidence in the conclusions stated in the documents. For each document specific data needs have been identified and I will not recount these here. However, I would like to recount for you some of the major generic issues that have been repeatedly encountered:

- 1) the validity of extrapolations from high levels of exposure to levels encountered by the public
- 2) the validity of extrapolation from laboratory animal species to man including the correlation of data derived from epidemiological and laboratory animal studies
- 3) the value of short-term tests for predicting late occurring effects of exposure to toxic agents
- 4) the extent of interaction (antagonism, synergism or additivity) resulting from exposure to different agents

- 5) the utility of dose-response derived from one route of exposure (such as ingestion) for predicting dose-response relationships for a second route of exposure (such as inhalation)
- 6) the inadequacies of information on current exposures of the population and methods for improving assessments of population exposure.

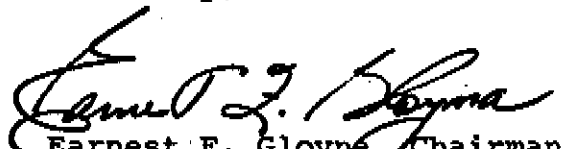
In each of these areas additional research is needed to provide data for improving the scientific basis for regulations issued by the Agency. It should be noted that in some cases improved data might provide a basis for not regulating particular materials or for relaxing current regulations.

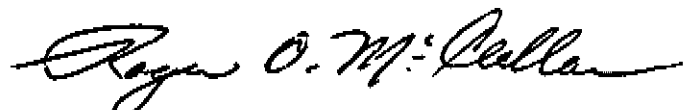
As you are well aware, inappropriate regulations based on an inadequate data base can be costly to society either in terms of the cost of compliance or health effects that might have otherwise been avoided. Thus, it is our opinion that the expenditures of funds for research to improve the data base for regulations is cost-effective. In the absence of data there is a tendency on the part of many individuals to over-estimate the risk to public health of materials present in the environment.

Since much of the needed research is long-term in nature, inadequate research support today is a long-term penalty on society.

Please let the Committee know if they can assist you in any way in planning the future course of the Agency's important environmental health research program.

Sincerely,


Earnest F. Gloyne, Chairman
Executive Committee


Roger O. McClellan, DVM
Chairman
Environmental Health Committee

cc: Dr. John W. Hernandez, Jr.
Dr. Courtney Riordan
Dr. Terry F. Yosie